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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,528	IDEKER, RAYMOND E.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) *1-18,37-54 and 73-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-36,55-72 and 91-107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-18, 37-54 and 73-90, drawn to a method, apparatus and computer program product for defibrillating a heart in fibrillation, classified in class 607, subclass 5.

   II. Claims 19-36, 55-72 and 91-107, drawn to a method, apparatus and computer program product for reducing an occurrence of fibrillation of a heart, classified in class 607, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not discloses as capable of being used together, they have different modes of operation and different effects. Specifically, Invention I requires the detection of fibrillation in the heart while Invention II does not. Invention II only requires the detection of a premature contraction of the heart which is not synonymous with a fibrillation. Also, Invention I results in the termination of fibrillation while Invention II does not. Invention II is merely for prevention of fibrillation or reduction of the occurrence of fibrillation in a heart.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Robert Crouse on January 23, 2006 a provisional election was made without traverse to prosecute the invention of Group II, claims 19-36, 55-72 and 91-107. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-18, 37-54 and 73-90 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

5. Claims 24, 30-32, 59, 65, 95 and 101 are objected to because of the following informalities: there appears to be multiple typographical errors in the first line of each claim regarding each claims dependency. Specifically, the Examiner suggests:

-- changing Claim 24 from "A method according to Claim 19" to recite "A method according to Claim 22" to avoid any antecedent basis problems.

-- changing Claim 30 from "A method according to Claim 27" to recite "A method according to Claim 28" to avoid any antecedent basis problems.

-- changing Claim 31 from "A method according to Claim 28" to recite "A method according to Claim 30" to avoid any antecedent basis problems.

-- changing Claim 32 from "A method according to Claim 29" to recite "A method according to Claim 31" to avoid any antecedent basis problems.

-- changing Claim 59 from "A system according to Claim 55" to recite "A system according to Claim 57" to avoid any antecedent basis problems.

-- changing Claim 65 from "A system according to Claim 62" to recite "A system according to Claim 63" to avoid any antecedent basis problems.

-- changing Claim 95 from "A computer program product according to Claim 91" to recite "A computer program product according to Claim 93" to avoid any antecedent basis problems.

-- changing Claim 101 from "A computer program product according to Claim 98" to recite "A computer program product according to Claim 99" to avoid any antecedent basis problems.

The Examiner is prosecuting the application with the new dependencies throughout the claims. Appropriate correction of all the objected claims is required.

6. Claim 62 is objected to because of the following informalities: the phrase "during fibrillation" in the third line of the claim appears to be a typographical error. The Examiner suggest deleting the phrase so that the third line of the claim reads "mean for applying, during heart activity characterized by . . . ". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 23, 29, 58, 64, 94 and 100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it is indefinite as to whether the "first wave front" is a wave front of the electrical stimulus applied to a fastest activating region or if the "first wave front" is "mother rotor" of the fastest activating region. The Examiner is prosecuting the Application as "the first wave front" being a mother rotor of the fastest activating region due to Applicant's disclosure. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 19-20, 27, 55, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Ideker et al. (U.S. 5,107,834) (herein Ideker '834). As to Claims 19-20 and 27, Ideker discloses a method comprising detecting a premature contraction of the heart for a plurality of beats via arrhythmia detector 16. Ideker '834 also discloses that arrhythmia detector 16 may be one of several types known in the art which are capable of analyzing the electrical cardiac activity and determining if and what type of arrhythmia exists whether it be a tachycardia or a fibrillation (see Ideker '834 column 3, lines 55-66). Ideker '834 further discloses that an electrical stimulus (i.e. a biphasic defibrillation waveform) is applied to a region of the heart that is likely to contain a fastest activation region by electrodes placed at "assumed locations" such as the base of the left ventricle (patch electrode A), in the septum (distal electrode positioned in the right ventricular outflow tract OT), adjacent to the pulmonary veins (SVC electrode and CS electrode) or between the pulmonary vein and a left atrial appendage (CS electrode) (see Ideker '834 Fig. 1, column 2, lines 24-39, column 3, lines 67-68 and column 4, lines 1-41).

The Examiner makes reference to Applicant's disclosure, page 11 where the "assumed locations" of the myocardium likely to contain a fastest activating region are listed at lines 13-19. In addition to the electrodes of Ideker '834 being placed at these "assumed locations" of the myocardium likely to contain a fastest activating region, Ideker '834 discloses that the method

carried out by the system of Fig. 1 depolarizes substantially "the entire myocardium" (see Ideker '834 Abstract and column 2, lines 64-68). The Examiner takes the position that such a system which utilizes an electrical stimulus to depolarize substantially "the entire myocardium" will stimulate any region of the heart that is "likely" to contain a fastest activating region. The Examiner also takes the position that since the method of Ideker '834 is capable of applying the electrical stimulus to the heart after detection of any type of arrhythmia capable of being classified via arrhythmia detector 16 (see Ideker '834 Abstract and column 3, lines 50-66), the method is inherently capable of reducing the occurrence of fibrillation of a heart.

11. As to Claims 55 and 62, Ideker '834 discloses a system comprising an electronic circuitry portion 10 and an implantable lead configuration 12 (see Ideker '834 Fig. 1) comprising means for detecting a premature contraction of the heart for a plurality of beats via arrhythmia detector 16. Ideker '834 also discloses that arrhythmia detector 16 may be one of several types known in the art which are capable of analyzing the electrical cardiac activity and determining if and what type of arrhythmia exists whether it be a tachycardia or a fibrillation (see Ideker '834 column 3, lines 55-66). Ideker '834 further discloses that an electrical stimulus (i.e. a biphasic defibrillation waveform) is applied to a region of the heart that is likely to contain a fastest activation region by electrodes placed at "assumed locations" such as the base of the left ventricle (patch electrode A), in the septum (distal electrode positioned in the right ventricular outflow tract OT), adjacent to the pulmonary veins (SVC electrode and CS electrode) or between the pulmonary vein and a left atrial appendage (CS electrode) (see Ideker '834 Fig. 1, column 2, lines 24-39, column 3, lines 67-68 and column 4, lines 1-41).

The Examiner makes reference to Applicant's disclosure, page 11 where the "assumed locations" of the myocardium likely to contain a fastest activating region are listed at lines 13-19. In addition to the electrodes of Ideker '834 being placed at these "assumed locations" of the myocardium likely to contain a fastest activating region, Ideker '834 discloses that the method carried out by the system of Fig. 1 depolarizes substantially "the entire myocardium" (see Ideker '834 Abstract and column 2, lines 64-68). The Examiner takes the position that such a system which utilizes an electrical stimulus to depolarize substantially "the entire myocardium" will stimulate any region of the heart that is "likely" to contain a fastest activating region. The Examiner also takes the position that since the method and system of Ideker '834 are capable of applying the electrical stimulus to the heart after detection of any type of arrhythmia capable of being classified via arrhythmia detector 16 (see Ideker '834 Abstract and column 3, lines 50-66), the method is inherently capable of reducing the occurrence of fibrillation of a heart.

12. Claims 19-20, 27, 55 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Ideker et al. (U.S. 5,224,476) (herein Ideker '476). As to Claims 19-20, 27, 55 and 62, Ideker '476 discloses a method and apparatus 10 which detect a premature contraction of the heart characterized by a tachycardia or a fibrillation for a plurality of beats via arrhythmia detector 22. Ideker '476 also discloses that arrhythmia detector 22 may be one of several types known in the art which are capable of analyzing the electrical cardiac activity and determining if and what type of arrhythmia exists whether it be a tachycardia or a fibrillation (see Ideker '476 column 4, lines 35-45). Ideker '476 further discloses that an electrical stimulus (i.e. a biphasic waveform or a triphasic waveform) is applied to a region of the heart that is likely to contain a fastest activation region by electrodes placed at "assumed locations" such as the base of the left

ventricle (patch electrode A), in the septum (distal electrode positioned in the right ventricular outflow tract OT), adjacent to the pulmonary veins (SVC electrode and CS electrode) or between the pulmonary vein and a left atrial appendage (CS electrode) (see Ideker '476 Fig. 1, column 2, lines 46-68 and column 3, lines 19-53).

The Examiner makes reference to Applicant's disclosure, page 11 where the "assumed locations" of the myocardium likely to contain a fastest activating region are listed at lines 13-19. In addition to the electrodes of Ideker '476 being placed at these "assumed locations" of the myocardium likely to contain a fastest activating region, Ideker '476 discloses that the method and apparatus may be for controlling tachycardia or fibrillation (see Ideker '476 Title, Abstract and column 2, lines 46-68 and column 2, lines 64-68). It is inherent that tachycardia, if left untreated, may develop into a fibrillation so the Examiner takes the position that a method for controlling or halting tachycardia will inherently "reduce an occurrence of fibrillation of a heart". The Examiner also takes the position that since the method of Ideker '476 is capable of applying the electrical stimulus to the heart after detection of any type of arrhythmia capable of being classified via arrhythmia detector 22 the method and system are inherently capable of reducing the occurrence of fibrillation of a heart.

13. Claims 91 and 98 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ideker '476. Ideker '476 discloses a method and apparatus 10 which detect a premature contraction of the heart characterized by a tachycardia or a fibrillation for a plurality of beats via arrhythmia detector 22. Ideker '476 also discloses that arrhythmia detector 22 may be one of several types known in the art which are capable of analyzing the electrical cardiac activity and determining if and what type of

arrhythmia exists whether it be a tachycardia or a fibrillation (see Ideker '476 column 4, lines 35-45). Ideker '476 further discloses that an electrical stimulus (i.e. a biphasic waveform or a triphasic waveform) is applied to a region of the heart that is likely to contain a fastest activation region by electrodes placed at "assumed locations" such as the base of the left ventricle (patch electrode A), in the septum (distal electrode positioned in the right ventricular outflow tract OT), adjacent to the pulmonary veins (SVC electrode and CS electrode) or between the pulmonary vein and a left atrial appendage (CS electrode) (see Ideker '476 Fig. 1, column 2, lines 46-68 and column 3, lines 19-53). Ideker '476 further discloses that the method carried out by the system 10 is controlled via a controller 26 (see Ideker '476 Fig. 1, column 4, lines 25-35 and column 6, lines 15-23). It is inherent or at least obvious to one having ordinary skill in the art that controller 26 be a conventional computer program product comprising a computer readable medium comprising instructions to carry out the method of the system 10 of Ideker '476.

The Examiner makes reference to Applicant's disclosure, page 11 where the "assumed locations" of the myocardium likely to contain a fastest activating region are listed at lines 13-19. In addition to the electrodes of Ideker '476 being placed at these "assumed locations" of the myocardium likely to contain a fastest activating region, Ideker '476 discloses that the method and apparatus may be for controlling tachycardia or fibrillation (see Ideker '476 Title, Abstract and column 2, lines 46-68 and column 2, lines 64-68). It is inherent that tachycardia, if left untreated, may develop into a fibrillation so the Examiner takes the position that a method for controlling or halting tachycardia will inherently "reduce an occurrence of fibrillation of a heart". The Examiner also takes the position that since the method of Ideker '476 is capable of applying the electrical stimulus to the heart after detection of any type of arrhythmia capable of being

classified via arrhythmia detector 22 the method and system are inherently capable of reducing the occurrence of fibrillation of a heart.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 21, 33-36, 56 and 68-72 are rejected under 35 U.S.C. 103(a) as being obvious over Ideker '834. Ideker '834 discloses the claimed invention but does not expressly discloses the steps of locating a fastest activating region by inducing fibrillation and determining at least one of a monophasic action potential (MAP) reading associated with the fibrillating heart, a refractory period associated with the heart using premature stimulation and a power spectrum analysis to provide a spectrum with peak power at a highest frequency or by simply determining a refractory period associated with the heart using a premature contraction or determining an activation recovery interval or determining a MAP. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method and system as taught by Ideker '476 with such ways to locate the fastest activating region, because Applicant has not disclosed that such a localizing method provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the mapping technique for electrode configuration and/or placement as taught by Ideker '834, because it provides preferable electrode

placement for the best defibrillation of the myocardium and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Ideker '834.

Therefore, it would have been an obvious matter of design choice to modify Ideker '834 to obtain the invention as specified in the claims.

16. Claims 21, 33-36, 56, 68-72, 92 and 104-107 are rejected under 35 U.S.C. 103(a) as being obvious over Ideker '476. Ideker '476 discloses the claimed invention but does not expressly discloses the steps of locating a fastest activating region by inducing fibrillation and determining at least one of a monophasic action potential (MAP) reading associated with the fibrillating heart, a refractory period associated with the heart using premature stimulation and a power spectrum analysis to provide a spectrum with peak power at a highest frequency or by simply determining a refractory period associated with the heart using a premature contraction or determining an activation recovery interval or determining a MAP. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method and system as taught by Ideker '476 with such ways to locate the fastest activating region, because Applicant has not disclosed that such a localizing method provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the mapping technique for electrode configuration and/or placement as taught by Ideker '476, because it provides preferable electrode placement for the best defibrillation of the myocardium and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Ideker '476.

Therefore, it would have been an obvious matter of design choice to modify Ideker '476 to obtain the invention as specified in the claims.

17. Claims 22-26, 28-32, 57-61 and 63-67 are rejected under 35 U.S.C. 103(a) as being obvious over Ideker '834 in view of Huang et al. (*Regional Differences in Ventricular Fibrillation in the Open-Chest Porcine Left Ventricle*. Circ. Res. 2002; 733-740) (herein Huang). As to Claims 22, 28, 57 and 63, Applicant differs from Ideker '834 in that the fastest activating region comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region. The Examiner takes the position that a fastest activating region inherently comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region since this is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a fastest activating region contains a stable reentrant circuit called a mother rotor, which has a shorter refractory period than the remainder epicardial tissue (see Huang page 733).

18. As to Claims 24, 30, 59 and 65, the Examiner takes the position that a reentrant circuit is synonymous with a closed pathway on the heart since the definition of "circuit" is a closed pathway.

19. As to Claims 25-26, 31-32, 60-61 and 66-67, the Examiner takes the position that a "mother rotor" as well known in the art is synonymous with a wave front that propagates along a reentrant circuit (i.e. closed pathway) from a starting point to an ending point that are adjacent to each other as in a circle or reentrant loop.

20. As to Claims 23, 29, 58 and 64, Applicant differs from Ideker '834 in that a first wave front propagates along a closed pathway on the fibrillating heart where the first wave front generates at least a second wave front that propagates on the fibrillating hear outside the fastest activation region. The Examiner takes the position that a mother rotor is synonymous with a

fastest activating region's first wave front. The Examiner also takes the position that mother rotors spawn daughter rotors, which is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a mother rotor spawns wavefronts that propagate to maintain ventricular fibrillation elsewhere or other than the location of the fastest activating region's mother rotor (see Huang pages 733-740).

21. Claims 22-26, 28-32, 57-61, 63-67, 93-97 and 99-103 are rejected under 35 U.S.C. 103(a) as being obvious over Ideker '476 in view of Huang. As to Claims 22, 28, 57, 63, 93 and 99, Applicant differs from Ideker '476 in that the fastest activating region comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region. The Examiner takes the position that a fastest activating region inherently comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region since this is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a fastest activating region contains a stable reentrant circuit called a mother rotor, which has a shorter refractory period than the remainder epicardial tissue (see Huang page 733).

22. As to Claims 24, 30, 59, 65, 95 and 101, the Examiner takes the position that a reentrant circuit is synonymous with a closed pathway on the heart since the definition of "circuit" is a closed pathway.

23. As to Claims 25-26, 31-32, 60-61, 66-67, 96-97 and 102-103, the Examiner takes the position that a "mother rotor" as well known in the art is synonymous with a wave front that propagates along a reentrant circuit (i.e. closed pathway) from a starting point to an ending point that are adjacent to each other as in a circle or reentrant loop.

As to Claims 23, 29, 58, 64, 94 and 100, Applicant differs from Ideker '476 in that a first wave front propagates along a closed pathway on the fibrillating heart where the first wave front generates at least a second wave front that propagates on the fibrillating hear outside the fastest activation region. The Examiner takes the position that a mother rotor is synonymous with a fastest activating region's first wave front. The Examiner also takes the position that mother rotors spawn daughter rotors, which is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a mother rotor spawns wave fronts that propagate to maintain ventricular fibrillation elsewhere or other than the location of the fastest activating region's mother rotor (see Huang pages 733-740).

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Obel et al. (U.s. 5,865,838) (herein Obel) discloses a method, system and computer program product that defibrillates atrial fibrillations by applying an electrical stimulus to a fastest activating region. The fastest activating region is determined via power spectrum analysis.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 02/06/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766